K-*ASSAY*®

RF Calibrator (Ver.2)

Cat. No. KAI-231C

INTENDED USE

The **K-*ASSAY*®** RF Calibrator (Ver.2) is intended to be used to calibrate the **K-*ASSAY*®** RF (Ver.2) immunoturbidimetric assay. FOR *IN VITRO* DIAGNOSTIC USE.

SUMMARY

The calibrators in this kit are human serum tested and found negative for HBsAg and HIV Ab. They contain known quantities of rheumatoid factor (RF). These are to be used as calibrators with the **K-*ASSAY*®** RF (Ver.2) assay.

KIT COMPOSITION

Calibrators (Liquid Stable)

MATERIALS PROVIDED

Calibrator A	Sodium Chloride (150 mM)	1 x 1 mL
Calibrators B-F	Human serum	5 x 1 mL

Calibrators B-F contain pooled human serum with assigned values for rheumatoid factor.

WARNINGS AND PRECAUTIONS

FOR *IN VITRO* DIAGNOSTIC USE. ℞ only.

Not to be used internally in humans or animals. Normal precautions exercised in handling laboratory reagents should be followed.

Do not mix or use calibrators from one test kit with those from a different lot number.

Do not use calibrators past their expiration date stated on each container label.

Do not pipette by mouth. Avoid ingestion and contact with skin.

These Calibrators contain pooled human serum from RF-positive human serum. The serum has been tested and found non-reactive for the presence of HBsAg and HIV antibody by an FDA approved method. However, it is not possible to guarantee that any human source material is free of these or other infectious agents.

Therefore, all products that contain human source material should be handled in accordance with good laboratory practices and appropriate control. See the National Institute of Health Manual, "Biosafety in Microbiology and Biomedical Laboratories," 2nd ed., 1988.

Calibrators in this kit contain < 0.1% w/v sodium azide as a preservative. Sodium azide may form explosive compounds in metal drain lines. When disposing of calibrators through plumbing fixtures, flush with copious amounts of water. For further information, refer to "Decontamination of Laboratory Sink Drains to Remove Azide Salts," in the Manual Guide-Safety Management No. CDC-22 issued by the Centers for Disease Control, Atlanta, GA.

CALIBRATOR PREPARATION

The calibrators are ready to use and do not require reconstitution.

STORAGE AND HANDLING

All calibrators should be stored refrigerated (2-8°C). Return all calibrators to 2-8°C promptly after use. Unopened calibrators can be used until the expiration date indicated on the package and bottle labels.

CALIBRATOR STABILITY

Discard calibrators if they become contaminated. Evidence of cloudiness or particulate material in solution is cause to discard. Opened bottles of calibrators can be used for 1 month if stored at 2-8°C.

INSTRUMENT

Measurements of absorbance are to be made with a clinical chemistry analyzer able to accurately read absorbances. Refer to the instrument manual from the manufacturer regarding the following:

a) Use or function
b) Installation procedures and requirements
c) Principles of operation
d) Performance characteristics, operating instructions
e) Calibration procedures including materials and / or equipment to be used
f) Operational precautions, limitations, and hazards
g) Service and maintenance information

PROCEDURE

Materials Supplied

Calibrators should be used as specified in the **K-*ASSAY*®** RF (Ver.2) assay package insert.

Calibrator A	1 x 1 mL
Calibrator B	1 x 1 mL
Calibrator C	1 x 1 mL
Calibrator D	1 x 1 mL
Calibrator E	1 x 1 mL
Calibrator F	1 x 1 mL

Materials Required But Not Supplied

K-*ASSAY*® RF (Ver.2) Assay

Two-Reagent Clinical Chemistry Analyzer:
- Capable of accurate absorbance readings.
- Capable of accurately dispensing the required volumes
- Capable of maintaining 37°C

Details of Procedure

NOTE: Allow all reagents and specimens to come to room temperature. Mix all reagents gently before using.

The **K-*ASSAY*®** RF Calibrator (Ver.2) is assayed using the same procedure as the patient test samples run in the test procedure. See package insert from the **K-*ASSAY*®** RF (Ver.2) assay for details.

CALIBRATOR VALUES

The values of the **K-*ASSAY*®** RF Calibrator (Ver.2) are traceable to the NIBSC Rheumatoid Arthritis Serum, 64/002. Based upon this standardization, results are reported in International Units (IU)/mL.

A	B	C	D	E	F	
0	15	75	150	300	600	IU/mL

The expected values for the **K-*ASSAY*®** RF Calibrator (Ver.2) are continually being revised through ongoing quality assurance. As a result, the expected values may change from lot to lot. Please refer to the package insert for each lot for the exact calibrator values.

LABELING SYMBOLS

REF	Catalog Number
	Expiration or "Use By" Date
LOT	Lot Number
	Consult Package Insert for Instructions for Use
IVD	For *In Vitro* Diagnostic Use
CE	CE Mark Registered
℞	For Prescription Use Only
	Potential Human Biohazard
2°C 8°C	Temperature Limitation. Store between 2 and 8 degrees C
	Manufacturer
EC REP	Authorized Representative in the European Community

EU AUTHORIZED REPRESENTATIVE

CE

EC REP

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